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EXAMINER	
HILL, KEVIN KAI	

ART UNIT	PAPER NUMBER
1633	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/564,009	SHARIFI ET AL.	
	Examiner	Art Unit	
	KEVIN K. HILL	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,7,8,11-13 and 15-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,7,8,11-13 and 15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Amendments

Applicant's response and amendments, filed January 14, 2010, to the prior Office Action is acknowledged. Applicant has cancelled Claims 2, 6, 9-10 and 14, and added new claims, Claims 15-19. Applicant's new claims have been entered into the application as requested and will be examined on the merits herein.

Claims 1, 3-5, 7-8, 11-13 and 15-19 are under consideration.

Priority

This application is a 371 of PCT/US04/22827 filed July 15, 2004. Applicant's claim for the benefit of a prior-filed application parent provisional application 60/487,409, filed on July 15, 2003 under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Examiner's Note

Unless otherwise indicated, previous objections/rejections that have been rendered moot in view of the amendment will not be reiterated. The arguments in the January 14, 2010 response will be addressed to the extent that they apply to current rejection(s).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Objections

1. **The prior objection to Claim 13 to under 37 CFR 1.75(c),** as being of improper dependent form for failing to further limit the subject matter of a previous claim **is withdrawn** in light of Applicant's argument that transdifferentiation of the monocytic cell into an endothelial cell may occur in an *in vitro* or *in vivo* environment. Thus, Claim 13 further limits Claim 5 by distinguishing in which environment the transdifferentiation occurs, which the Examiner finds persuasive.

2. **The prior objection to Claim 14 under 37 CFR 1.75(c) is withdrawn** in light of Applicant's cancellation of the claim.

Claim Rejections - 35 USC § 101

3. **Claims 15-19 are rejected under 35 U.S.C. 101** because the claimed invention is directed to non-statutory subject matter. The claims are directed to "endothelial cells" transduced

with the claimed viral vector, without restriction as to where the cell is located. The scope of invention as claimed embraces a genetically modified human carrying in its genome or at least some of their cells a recombinant genetic material. Applicant's intended use of the monocytes transfected with a nucleic acid encoding PTN, thereby inducing differentiation into endothelial cells comprises promoting neovascularization to treat diseases such as ischemia by enhancing or promoting the activity of PTN (pg 8, ¶3). It is implicit that such patients are mainly human. Consequently, when read in light of the specification the claimed host cells would include host cells in human patients that would be an integral and inseparable part of the human. Such cells that are part of a human are non-statutory subject matter since they embrace the human that carries them. It is USPTO policy not to allow claims to humans (1077 O.G. 24 April 1987). See MPEP §2105.

The claims should be amended by insertion of "isolated" before "endothelial cells".

Appropriate correction is required.

Response to Arguments

Applicant argues that the endothelial cells do not exist in nature, and thus can be regarded as "by hand of man", and thus is patentable subject matter.

Applicant's argument(s) has been fully considered, but is not persuasive. Applicant's argument is not on point because the Examiner has not put forth the position that the endothelial cells are not "by hand of man".

Rather, the substantive issue is that the scope of invention as claimed embraces a genetically modified human carrying in its genome or at least some of their cells a recombinant genetic material. Applicant's intended use of the monocytes transfected with a nucleic acid encoding PTN, thereby inducing differentiation into endothelial cells comprises promoting neovascularization to treat diseases such as ischemia by enhancing or promoting the activity of PTN (pg 8, ¶3). It is implicit that such patients are mainly human. Consequently, when read in light of the specification the claimed host cells would include host cells in human patients that would be an integral and inseparable part of the human. Such cells that are part of a human are non-statutory subject matter since they embrace the human that carries them. It is USPTO policy not to allow claims to humans (1077 O.G. 24 April 1987). See MPEP §2105.

Claim Rejections - 35 USC § 112

4. **The prior rejection of Claim 14 under 35 U.S.C. 112 first paragraph**, as failing to comply with the written description requirement **is withdrawn** in light of Applicant's cancellation of the claim.

Claim Rejections - 35 USC § 103

5. **Claims 1 and 11 stand rejected under 35 U.S.C. 103(a)** as being unpatentable over Havemann et al (*of record) in view of Souttou et al (2001; *of record in IDS) and Powers et al (2002; *of record).

Response to Arguments

Applicant continues to argue that Havemann et al do not reasonably teach the use of PTN to obtain endothelial cells. The disclosure of PTN is in the context of a possible growth factor, selected from a list of at least 33 other growth factors, that can be used in the culture medium for mononuclear cells to influence differentiation, survival, migration and vascularization. There is no indication of which growth factor is responsible for differentiation of mononuclear cells into endothelial cells.

Applicant's argument(s) has been fully considered, but is not persuasive. The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed. *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). In the instant case, Havemann et al clearly disclose PTN as a growth factor used in the step of culturing monocytes to differentiate into endothelial-like cells or endothelial progenitor cells.

The Examiner maintains the position that one of ordinary skill in the art, upon reading Havemann et al in view of Souttou et al and Powers et al can reasonably draw a conclusion that PTN may be used for inducing differentiation of monocytic cells to endothelial cells.

Applicant argues that Havemann et al do not teach which growth factor effects differentiation, survival, migration or vascularization. Thus it is not obvious or within the skill of one of ordinary skill in the art to conclude that PTN is responsible for differentiation without undue experimentation.

Applicant's argument(s) has been fully considered, but is not persuasive. Havemann et al disclose a small list of growth factors to be used when differentiating monocytic cells to endothelial cells. It is unclear exactly what cell culture method step Applicant considers to be undue experimentation for the ordinary artisan. At the time of the instantly asserted invention

(priority date of July, 2003), cell culture techniques were routinely practiced for several decades by the ordinary artisan, and it was routine in the art to apply PTN to cultured cells at various concentrations and for various amounts of time (Powers). Furthermore, the ordinary artisan need only provide PTN to the monocytes and observe the corresponding effect.

Applicant argues that PTN was not contemplated by Havemann et al to be a gene to be expressed in the endothelial cells, as per [0191] referring to VEGF and FGF.

Applicant's argument(s) has been fully considered, but is not persuasive. Applicant appears to exercise a narrow interpretation of [0191]. However, the Examiner respectfully reminds Applicant that VEGF and FGF are species within the same genus that embraces PTN [0037]. Thus, it is the Examiner's position that those of ordinary skill in the art reading Havemann et al in view of Souttou et al and Powers et al would reasonably conclude that the disclosure of VEGF and FGF in [0191] are but *examples* [emphasis added] as evidenced by "for example" [0191] and the reasonably refer to other angiogenic growth factors, e.g. PTN [0037].

Applicant argues that Souttou et al teach PTN to be responsible for proliferation, migration and survival, but not inducing differentiation as per Havemann et al.

Applicant's argument(s) has been fully considered, but is not persuasive. Applicant appears to have overlooked the general knowledge available in the prior art, wherein PTN was recognized in the prior art to be involved in growth and differentiation (for example, Deuel et al, 2002; *of record in IDS; Pufe et al, 2003; *of record in IDS). Thus, the Examiner maintains the position that one of ordinary skill in the art, upon reading Havemann et al in view of Souttou et al and Powers et al can reasonably draw a conclusion that PTN may be used for inducing differentiation of monocytic cells to endothelial cells.

Applicant argues that Havemann et al do not teach the monocytic cells to be transduced with the retrovirus. Rather, Havemann et al teaches using a viral vector in the endothelial cells.

Applicant's argument(s) has been fully considered, but is not persuasive. Applicant appears to have overlooked that Havemann et al disclose the transfection of mononuclear cells

with a nucleic acid construct for gene therapy, wherein the construct comprises an effector gene [0032], the effector gene being a growth factor [0047], the growth factor including PTN [0074].

Applicant continues to argue that the Examiner has exercised impermissible hindsight in order to reject the claims.

Applicant's argument(s) has been fully considered, but is not persuasive. In response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In the instant case, the Examiner has taken into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made.

Applicant continues to argue that the rationale provided by the Examiner does not support the rejection under §103(a) because the results would not have been predictable to the ordinary artisan and there would not be a reasonable expectation of success. The Examiner has not shown that the ordinary artisan would find that using a monocytic cell transduced with a retrovirus expressing PTN would predictably transdifferentiate into an endothelial cell. Havemann et al made no indication of which growth factor is responsible for differentiation of the mononuclear cells into endothelial cells.

Applicant's argument(s) has been fully considered, but is not persuasive. In response to Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Havemann et al clearly disclose PTN as a growth factor used in the step of culturing monocytes to differentiate into endothelial-like cells or endothelial progenitor cells. Souttou et al taught that PTN is an angiogenic factor acting on endothelial cell proliferation, migration, survival, and capillary-like structure formation (pg 64, col. 1, last ¶). The prior art recognized that PTN has autocrine and paracrine stimulatory activities in cells expressing both PTN and the PTN receptor (Powers et al, pg 14155, col. 1, ¶4). While Havemann et al do not teach *ipsis verbis* that the mononuclear cells/monocytes express the PTN receptor, those of ordinary skill in the art would reasonably understand that the PTN receptor is necessarily present because the mononuclear cells/monocytes are disclosed to respond to PTN to give rise to endothelial cells. Thus, the expression of an effector transgene in the mononuclear cells [which includes monocytes] (Havemann) encoding PTN (Souttou) would be reasonably expected to achieve autocrine and paracrine stimulatory activities (Powers), promoting the differentiation of the mononuclear cells into endothelial cells (Havemann).

6. **Claim 3 stands rejected under 35 U.S.C. 103(a)** as being unpatentable over Havemann et al (*of record) in view of Souttou et al (2001; *of record in IDS) and Powers et al (J2002; *of

record), as applied to Claims 1 and 11 above, and in further view of Kume et al (2000; *of record).

Response to Arguments

Applicant argues that Kume et al do not cure the defect of Havemann et al, Souttou et al and Powers et al.

Applicant's argument(s) has been fully considered, but is not persuasive. The Examiner's response to Applicant's argument(s) regarding Havemann et al, Souttou et al and Powers et al are discussed above and incorporated herein. Applicant does not contest the teachings of Kume et al as applied to the obviousness to substitute the retroviral expression vector by Havemann et al with a bicistronic retroviral expression vector as taught by Kume et al, with a reasonable expectation of success because the simple substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

7. **Claim 4 stands rejected under 35 U.S.C. 103(a)** as being unpatentable over Havemann et al (*of record) in view of Souttou et al (2001; *of record in IDS), Powers et al (2002; *of record) and Kume et al (2000; *of record), as applied to Claims 1, 3 and 11 above, and in further view of Pufe et al (2003; *of record in IDS), Howett et al (*of record) and Eslami et al (2001; *of record).

Response to Arguments

Applicant argues that Pufe et al, Howett et al and Eslami et al do not cure the defect of Havemann et al, Souttou et al, Powers et al and Kume et al.

Applicant's argument(s) has been fully considered, but is not persuasive. The Examiner's response to Applicant's argument(s) regarding Havemann et al, Souttou et al, Powers et al and Kume et al are discussed above and incorporated herein. Applicant does not contest the teachings of Pufe et al, Howett et al and Eslami et al as applied to the obviousness to substitute a first mononuclear/monocyte cell with a second monocyte cell, specifically THP-1, with a reasonable expectation of success because the simple substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

8. **Claim 12 stands rejected under 35 U.S.C. 103(a)** as being unpatentable over Havemann et al (*of record) in view of Souttou et al (2001; *of record in IDS), Powers et al (2002; *of record), Kume et al (2000; *of record), Pufe et al (2003; *of record in IDS), Howett et al (*of record) and Eslami et al (2001; *of record), as applied to Claims 1, 3-4 and 11 above, and in further view of Kawamoto et al (Circulation 103:634-637, 2001).

Response to Arguments

Applicant argues that Kawamoto et al do not cure the defect of Havemann et al, Souttou et al, Powers et al, Kume et al, Pufe et al, Howett et al and Eslami et al.

Applicant's argument(s) has been fully considered, but is not persuasive. The Examiner's response to Applicant's argument(s) regarding Havemann et al, Souttou et al, Powers et al, Kume et al, Pufe et al, Howett et al and Eslami et al are discussed above and incorporated herein.

Applicant does not contest the teachings of Kawamoto et al as applied to the obviousness to substitute substitute the *in vitro* transdifferentiation step as taught by Havemann et al with an *in vivo* transdifferentiation step, with a reasonable expectation of success because the simple substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention, the motivation being that PTN has been repeatedly reported to induce the proliferation of endothelial cells and is an art-recognized angiogenic factor (Pufe) and Kawamoto et al successfully demonstrated the ability of monocytes to transdifferentiate into endothelial cells and incorporate at sites of neovascularization when implanted *in vivo*, thereby improving blood flow from an ischemic event.

9. **Claims 5 and 13 stand and Claims 15 and 18 are newly rejected under 35 U.S.C. 103(a)** as being unpatentable over Havemann et al (*of record) in view of Souttou et al (2001; *of record in IDS) and Powers et al (2002; *of record).

Response to Arguments

Applicant argues that Havemann et al, Souttou et al and Powers et al fail to render obvious the endothelial cell produced via transdifferentiation of a monocytic cell, for reasons discussed above.

Applicant's argument(s) has been fully considered, but is not persuasive. The Examiner's response to Applicant's argument(s) regarding Havemann et al, Souttou et al and Powers et al are discussed above and incorporated herein.

10. **Claim 7 stands and Claim 16 is newly rejected under 35 U.S.C. 103(a)** as being unpatentable over Havemann et al (*of record) in view of Souttou et al (2001; *of record in IDS) and Powers et al (J2002; *of record), as applied to Claims 5, 13, 15 and 18 above, and in further view of Kume et al (2000; *of record).

Response to Arguments

Applicant argues that Kume et al do not cure the defect of Havemann et al, Souttou et al and Powers et al.

Applicant's argument(s) has been fully considered, but is not persuasive. The Examiner's response to Applicant's argument(s) regarding Havemann et al, Souttou et al and Powers et al are discussed above and incorporated herein. Applicant does not contest the teachings of Kume et al as applied to the obviousness to substitute the retroviral expression vector by Havemann et al with a bicistronic retroviral expression vector as taught by Kume et al, with a reasonable expectation of success because the simple substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

11. **Claim 8 stands and Claim 17 is newly rejected under 35 U.S.C. 103(a)** as being unpatentable over Havemann et al (*of record) in view of Souttou et al (2001; *of record in

IDS), Powers et al (2002; *of record) and Kume et al (2000; *of record), as applied to Claims 5, 7, 13, 15-16 and 18 above, and in further view of Pufe et al (2003; *of record in IDS), Howett et al (*of record) and Eslami et al (2001; *of record).

Response to Arguments

Applicant argues that Pufe et al, Howett et al and Eslami et al do not cure the defect of Havemann et al, Souttou et al, Powers et al and Kume et al.

Applicant's argument(s) has been fully considered, but is not persuasive. The Examiner's response to Applicant's argument(s) regarding Havemann et al, Souttou et al, Powers et al and Kume et al are discussed above and incorporated herein. Applicant does not contest the teachings of Pufe et al, Howett et al and Eslami et al as applied to the obviousness to substitute a first mononuclear/monocyte cell with a second monocyte cell, specifically THP-1, with a reasonable expectation of success because the simple substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

12. **Claim 19 is rejected under 35 U.S.C. 103(a)** as being unpatentable over Havemann et al (*of record) in view of Souttou et al (2001; *of record in IDS), Powers et al (2002; *of record), Kume et al (2000; *of record), Pufe et al (2003; *of record in IDS), Howett et al (*of record) and Eslami et al (2001; *of record), as applied to Claims 5, 7-8, 13 and 15-18 above, and in further view of Kawamoto et al (Circulation 103:634-637, 2001).

Claim interpretation: to the extent that the claims are drawn to an isolated endothelial cell that transdifferentiated from a monocyte *in vivo*, and the specification discloses figures of isolated tissue comprising said endothelial cell that transdifferentiated from a monocyte *in vivo* (Figures 5A-H), the Examiner interprets isolated tissue comprising endothelial cell(s) that transdifferentiated from a monocyte *in vivo* to fulfill the limitations of the claim.

Determining the scope and contents of the prior art.

Havemann et al do not teach the step of administering the genetically modified monocytes to a subject so that the transdifferentiation of said monocytes into endothelial cells occurs *in vivo*. However, at the time of the invention, Kawamoto et al taught the *in vivo* transplantation of endothelial progenitor cells obtained from mononuclear cells, and isolated tissue comprising endothelial cells that had transdifferentiated from said mononuclear cells *in vivo* (Figures 1 and 2).

Considering objective evidence present in the application indicating obviousness or nonobviousness.

It would have been obvious to one of ordinary skill in the art to substitute the *in vitro* transdifferentiation step as taught by Havemann et al with an *in vivo* transdifferentiation step, with a reasonable expectation of success because the simple substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. An artisan would be motivated to the *in vitro* transdifferentiation step with an *in vivo* transdifferentiation step because PTN has been repeatedly reported to induce the proliferation of endothelial cells and is an art-recognized angiogenic factor (Pufe) and Kawamoto et al successfully demonstrated the ability of monocytes to transdifferentiate into endothelial cells and incorporate at sites of neovascularization when implanted *in vivo*, thereby improving blood flow from an ischemic event.

The cited prior art meets the criteria set forth in both *Graham* and *KSR*, and the teachings of the cited prior art provide the requisite teachings and motivations with a clear, reasonable expectation of success. Thus, absent evidence to the contrary, the invention as a whole is *prima facie* obvious.

Conclusion

13. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to KEVIN K. HILL whose telephone number is (571)272-8036.

The Examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin K. Hill/
Examiner, Art Unit 1633